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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,198	07/29/2003	Yen-Lin Chen	U 014740-4	5680

7590 05/16/2005

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,198	CHEN ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *6-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/29/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

AD

DETAILED ACTION

Election/Restrictions

Applicants' election without traverse of Group I (claims 1-5) in the reply filed on 4/25/2005 is acknowledged.

Claims 6-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 4/25/2005.

Claims 1-5 are under examination in the instant office action.

Claim Objections

Claims 1-5 are objected to because of the following informalities:

Claim 1 contains abbreviated term GABA. Abbreviation in the first instance of claims should be explained upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims as written, do not sufficiently distinguish over nucleic acids, proteins, cells and antibodies as they exist naturally because the claims do not particularly point out any naturally occurring differences between the claimed products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v.*

Chakrabarty, 447 U.S. 393, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of inventor. e.g., by insertion of "Isolated" as taught on page 7, line 16 of specification. See MPEP 2105.

Claim Rejections - 35 USC § 112

Deposit

Claims 3-5 are rejected under 35 U.S.C. 112, *first paragraph,* as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to specific microbial strains *Monascus purpureus* M022 (ATCC PTA 4486) and *Monascus purpureus* M01033 (ATCC PTA 4485). Because the microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganisms are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the claimed microbial strains and it is not clear from the specification or record that the claimed microbial strains are readily available to the public. Although the deposits are made under the terms of the Budapest Treaty (specification page 4; ATCC deposit receipts), the affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the

depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent is presently missing from the records.

A declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,635,467 (Chen et al.) in the light of evidence by JP 2000279163.

Claims are directed to a mutant of *Monascus purpureus* that is derived from parent strain *Monascus purpureus* CCRC 31499 and that is capable to grow on rice and soybean powders and to produce non-toxic fermentation product(s) including GABA due to low amounts of citrinin.

US 6,635,467 (Chen et al.) discloses mutants of strain *Monascus purpureus* CCRC 31499 (col.3, lines 30-50) including stable mutant M011 (col. 3, line 51; page 1, lines 60-64 or example 2) wherein the mutants are capable to grow on rice and soybean powder and magnesium sulfate (col.3, lines 39-41) and to produce non-toxic fermentation products due to low amounts of citrinin (col. 1, lines 50-55and table 3). Citrinin is a fungal toxin (col. 1, line 30). Although the cited patent is primary concerned with production of yellow pigments during fermentation, the GABA product that is encompassed by the instant claims is one of permeation products of

microbial cultures belonging to *Monascus purpureus* on rice and soybean powders in the light of evidence by JP 2000279163 (English abstract).

Thus, the mutant(s) derived from the same parent strain *Monascus purpureus* CCRC 31499 of the cited patent anticipates the invention of the instant claims 1 and 2.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as anticipated by US 6,635,467 (Chen et al.) or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,635,467 (Chen et al.) in the light of evidence by JP 2000279163.

Claims are directed to a mutant of *Monascus purpureus* that is derived from parent strain *Monascus purpureus* CCRC 31499 and that is capable to grow on rice and soybean powders and to produce non-toxic fermentation product(s) including GABA due to low amounts of citrinin.

Some claims are further drawn to particular strains *Monascus purpureus* M022 (ATCC PTA 4486) and *Monascus purpureus* M01033 (ATCC PTA 4485).

US 6,635,467 (Chen et al.) is relied upon as explained above.

The cited patent discloses the mutant(s) derived from the same parent strain *Monascus purpureus* CCRC 31499 including mutant M011 that appear to be identical to the presently claimed strains M022 and M01033 since they are isolated from identical culture by identical process of mutagenesis. The referenced microorganisms appear to be identical to the presently claimed strains and are considered to anticipate the claimed microorganisms since they are capable to grow on rice and soybean powder and magnesium sulfate (col. 3, lines 39-41) and to produce non-toxic fermentation products due to low amounts of citrinin. Consequently, the claimed strains appear to be anticipated by the patent.

In the alternative, even if the claimed microorganisms are not identical to the referenced microorganisms with regard to some unidentified characteristics including GABA production, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganisms are likely to inherently possess the same characteristics of the claimed microorganisms particularly in view of the similar characteristics which they have been shown to share. Moreover, the GABA product is a *Monascus* fermentation product on rice and soybean powders in the light of evidence by JP 2000279163 (English abstract). Thus the presently claimed strains M022 and M01033 would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000279163 and JP 7274978.

Claims are directed to *Monascus* mutant(s) or cultures that are capable to grow on rice and soybean powders and to produce non-toxic fermentation product(s) including GABA due to low amounts of citrinin. Some claims are further drawn to particular strains *Monascus purpureus* M022 (ATCC PTA 4486) and *Monascus purpureus* M01033 (ATCC PTA 4485).

JP 7274978 teaches that microbial cultures and/or strains belonging to *Monascus* including *Monascus purpureus* are capable to produce non-toxic edible fermentation product(s) due to low amounts of citrinin (English abstract).

JP 2000279163 teaches that that microbial cultures and/or strains belonging to *Monascus* are capable to grow on rice and soybean powders and to produce edible and therapeutic fermentation product(s) including GABA products (English abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain *Monascus* cultures including *Monascus purpureus* producing non-toxic fermentation product(s) with GABA due to low amounts of citrinin with a reasonable expectation of success because the prior art demonstrates that *Monascus* cultures including *Monascus purpureus* are known to produce GABA and to have low

amounts of toxic citrinin. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. One of skill in the art would have been motivated to select cultures producing GABA and having low contents of citrinin for the expected benefits in obtaining edible and therapeutic fermentation products of *Monascus* cultures.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US 6,635,467 (Chen et al.).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to substantially similar, if not identical, mutant(s) of *Monascus purpureus* that is derived from parent strain *Monascus purpureus* CCRC 31499 that is

capable to grow on rice and soybean powder and to produce non-toxic fermentation products due to low amounts of citrinin.

The instant claims are broader and encompass an isolated mutant of *Monascus purpureus* that is derived from parent strain *Monascus purpureus* CCRC 31499 and that is capable to grow on rice and soybean powder and to produce non-toxic fermentation products (GABA) due to low amounts of citrinin.

The patented claims are narrower and directed to an isolated mutant of *Monascus purpureus* M011 (ATCC PTA-2496) that is derived from parent strain *Monascus purpureus* CCRC 31499 (page 1, lines 60-64) and that is capable to grow on rice and soybean powder (col. 5, table 3) and to produce non-toxic fermentation products (yellow pigments) due to low amounts of citrinin (table 3).

Accordingly, the claimed products in the patent of US 6,635,467 (Chen et al.) and in the present application are obvious variants. Therefore, the inventions as claimed are co-extensive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

May 12, 2005

VERA AFREMOVA

PRIMARY EXAMINER